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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Daijiro Kurosaka

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3774

NOTIFICATION DATE

DELIVERY MODE

05/12/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/554,206	Applicant(s) KUROSAKA ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17, 19-24 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17, 19-24 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/31/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 3-3-11 have been fully considered but are not persuasive or are moot in view of the new grounds of rejection set forth below.

Applicant argues the anterior surface of the lens at the boundary in Paul includes a step and sudden shift. Examiner disagrees, and maintains the claimed boundary on the anterior surface of the lens is readable on the smoothly contoured section of the optical lens in Paul et al. Figure 19 since it is between the support portion (haptic) and optic portion (central optic region) and may be interpreted as not being a "sudden shift". Figure 19 shows a rounded smooth transition 264 and sudden shift edge 266/262.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-17,19-24,33-35 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-16 each recite the term "sudden" which is a relative term lacking clear definition in the specification so as to ascertain what is met or not met by the scope of the term.

Claims 15,34,35 each recite the term "soft" which is a relative term lacking clear definition in the specification so as to ascertain what is met or not met by the scope of

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the term. Examiner recommends defining the relative rigidity between the PMMA and acrylic as harder and softer.

Claim 19 recites the term "substantially" which is not defined by the specification so as to ascertain what is within the scope of the claim.

Claim 22 recites the term "slightly" which is not defined by the specification so as to ascertain what is within the scope of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-17, 19-24, 33, and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. USPN 6468306 in view of JP 09-276303 ("Hoya", with reference to translation as provided in IDS).

Paul et al. disclose multiple edge configurations for intraocular lens in figures 4-20. Example dimensions are given in Tables I and II at column 8. The lens and haptics may be integrally molded into a single piece (col. 14 lines 10-21) and may be formed from hard PMMA or soft acrylics (col. 5 lines 41-67). The edges shown provide stepped faces as broadly claimed comprising a sudden shift, wall face nearly parallel to the optical axis, a step height of 0.05 mm or more (see Figure 4 and t1 in Tables I-II), a surface which is substantially orthogonal to the optical axis, a posterior portion near the

edge part rising toward the edge part in a posterior direction, and portions having acute and obtuse angled or curved portions. Figure 19 show a concavo-convex face into which the stepped face is formed which also meets claim 33.

With further respect to claim 15 (“no step on the anterior surface of the lens in the boundary”), the step in Paul is not due to the axial arrangement of the haptic-optic junction. The steps are present on a single face of the optic (see Figure 19, for example) and the claimed boundary is not limited to a single plane between the haptic and optic. Furthermore, the outer periphery (a bottom section of Figure 19 which would essentially include an annular ring) is readable on the claimed “boundary” which includes a step only on one side.

Paul is silent as to the haptics being formed of harder PMMA and the lens formed of softer acrylics. Hoya teach intraocular lens forming techniques wherein PMMA haptics and acrylic lenses may be integrally formed in order to securely mold a lens having multiple mechanical properties. See paragraphs 22, 29, and figure 1. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include PMMA haptics and acrylic lens to the lens disclosed in Paul et al. since such a combination is well known in the art as taught by Hoya in order to provide multiple mechanical properties to a unitary lens.

Regarding claims 34-35, Paul et al. is silent as to the exact steps taken to manufacture the lens but does describe at column 14 lines 10-21 that known techniques of molding and cutting may be used to form the shaped lenses. Hoya teach molding processes. Therefore it would have been obvious to one of ordinary skill in the

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art at the time of the invention to include the steps of molding, cutting, and grooving as such steps would be obvious, if not inherent, in view of the teachings of Paul et al. and Hoya since molding and cutting are well known manufacturing techniques.

Claims 15-17, 19-24, 33, and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamielle et al. USPN 6200344 ("Lamielle") in view of JP 09-276303 ("Hoya", with reference to translation as provided in IDS).

Lamielle disclose at figures 2 and 4 an IOL comprising two arm shaped members and an optic portion whereby the joint position comprises a posterior side stepped face/edge orthogonal to the optical axis (greater than 0.05 mm) and an anterior side smooth transition lacking a sudden shift. Regarding claims 21-23 a proximal region is curved or inclined at an acute or obtuse angle (depending on the point of reference and noting the the stepped face may be considered both surfaces about the abrupt posterior edge/angle).

Lamielle disclose the haptics and optics may be integrally formed into a single piece IOL using known techniques (c3:44-61) and teaches soft acrylic and PMMA materials are suitable (c6:19-58) but fails to explicitly disclose molding a soft acrylic optic and PMMA haptics. Hoya teach intraocular lens forming techniques wherein PMMA haptics and acrylic lenses may be integrally formed in order to securely mold a lens having multiple mechanical properties. See paragraphs 22, 29, and figure 1. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include PMMA haptics and acrylic lens to the lens disclosed in Lamielle

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since such a combination is well known in the art as taught by Hoya in order to provide multiple mechanical properties to a unitary lens.

Regarding claims 34-35, Lamielle et al. is silent as to the exact steps taken to manufacture the lens as described above but does describe at column 3 lines 44-61 that known techniques may be used to form the shaped lenses. Hoya teaches molding processes. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include the steps of molding, cutting, and grooving as such steps would be obvious, if not inherent, in view of the teachings of Paul et al. and Hoya since molding and cutting are well known manufacturing techniques to produce shaped optical components.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
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